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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,897	03/06/2002	Aneas Antoine	1417G P 703	9171
44444	7590	10/05/2005	EXAMINER	
BAXTER HEALTHCARE CORPORATION ONE BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			BOUCHELLE, LAURA A	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/091,897.

Applicant(s)

ANTOINE, ANEAS

Examiner

Laura A. Bouchelle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-8, 10, 12, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas (WO 98/0093037) in view of Hilbar et al (US 2002/0072706) or Parker et al (US 2003/0093037).

3. Regarding claim 1, Aneas discloses a device for connection between a closed recipient and a container comprising a neck whose opening is closed by a stopper. Aneas discloses a base adapted to be mounted on a recipient 3 and comprising a sleeve 12 with an inner bore 12a. Aneas further discloses a hollow needle 5, a plunger 15, adapted to slide in the bore and has an edge of sleeve opposite a stopper 3b provided with stop means 18 adapted to cooperate with complementary means 16 provided on the plunger 15 to lock it in a position of transfer.

4. Regarding claims 6 and 7, Aneas discloses hooks 54 projecting radially with respect to the sleeve that are provided with a nose.

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5. Regarding claim 8, Aneas discloses a second sleeve 22 disposed radially outside an interior sleeve 12.

6. Regarding claim 10, Aneas discloses a means for temporarily stopping the plunger in the disengaged position and states that the invention is in position fastened and locked on a first receptacle, and in the inactivated position of the plunger comprising the perforating means.

7. Regarding claim 12, Aneas discloses a ready-to-use assembly comprising a closed recipient containing a product 2, with the recipient being provided with a neck 2a whose opening is closed by a stopper 3, with a connection device 1 mounted on said recipient. See Figs. 2-4.

8. Aneas does not disclose a needle with a non-circular cross section, a sleeve with a non-circular cross-section, such that the needle can slide in the sleeve without the possibility of rotation.

9. Hilbar et al discloses a transluminal drug delivery catheter that teaches the use of a needle with a non-circular cross section 30 in conjunction with a non-circular sleeve 34 (paragraph 0061) in order to prevent rotation of the needle within the sleeve. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Aneas to have a non-circular needle and sleeve as taught by Hilbar to prevent unwanted rotation of the needle.

10. Parker et al discloses a hypodermic needle syringe that teaches the use of a non-circular needle hub 4 in conjunction with a non-circular sleeve 1.2 (paragraph 0030) in order to prevent axial rotation of the needle relative to the sleeve. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Aneas to be non-circular as taught by Parker to prevent unwanted rotation of the needle.

11. Claims 2 and 3 narrow the shape of the cross-section of the needle to an oval and polygonal outer cross section with the sleeve having an oval cross section. Hilbar and Parker teach using a needle and sleeve with a non-circular cross section in the same field of endeavor in order to prevent rotation of the spike. It would have been obvious to one of ordinary skill in the art at the time of invention to use an oval or polygonal cross section since the reference discloses using a non-circular cross section and oval is a non-circular shape.

12. Furthermore, the choice of a non-circular cross section in claims 1-3 would have been an obvious design choice. It would have been an obvious engineering design modification to change the shape of the cross section of the needle to a non-circular shape. Further, changing the shape of the needle does not affect the integrity of the invention.

13. Claims 4 and 5 differ from Aneas in calling for the stop means to comprise elastically deformable hooks while the complementary means on the plunger are bearing surfaces on a flange in one piece with the needle. Aneas does, however, teach the same elements in reverse. Aneas teaches a stop means that comprises elastically deformable hooks 16 on the plunger with a

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complementary bearing surface 18 on the sleeve. The integrity of the invention is not adversely impacted or affected by where the hooks and bearing surface are placed. The effect is the same regardless of if the hooks are on the plunger or if they are on the sleeve. It would have been obvious to one of ordinary skill in the art at the time of invention to rearrange the device and place the hooks on the plunger and the complementary means on the sleeve to act as a stop means. The effect is similar regardless of how the hooks and bearing surfaces are arranged.

14. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas in view of Hilbar or Parker and further in view of Thibault et al (WO 99/53886).

15. Claim 11 differs from the above teaching in calling for the stop means to comprise at least one hollow of the outer surface of the needle and at least one projection. Thibault teaches using a hollow on the outer surface of a needle (hollow 476, Fig. 10) that is engaged by a projection that extends from the inner radial surface of a sleeve 478 (Page 14, lines 27-29). See Fig. 11. It would have been obvious to one of ordinary skill in the art at the time of invention to modify Aneas to include a hollow in the needle and projection on the inner surface of the sleeve as taught by Thibault to keep the needle in a disengaged position.

16. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Aneas in view of Hilbar or Aneas in view of Parker further in view of Manera.

17. Claim 9 differs from the teachings above in calling for ribs that form a rigid barrier to rotation. Manera teaches using ribs connecting an inner sleeve 12 with a plunger 15 in order to form a rigid barrier for blocking rotation of the plunger with respect to the inner sleeve (Col. 4, lines 41-47). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Aneas to include ribs between the inner and outer sleeves as taught by Manera to prevent rotation of the sleeves with respect to each other.

#### ***Response to Arguments***

18. Applicant's arguments filed 6/16/2005 have been fully considered but they are not persuasive.

19. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the examiner finds that it is proper to combine the Aneas and Hilbar references since they are in the same area of endeavor. For the same reason, the examiner also finds it proper to combine the Aneas and Parker references. The motivation for these combinations is as stated in the above action.

***Conclusion***

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura A Bouchelle  
Examiner  
Art Unit 3763

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